

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

FEDERAL TRADE COMMISSION and

THE PEOPLE OF THE STATE OF NEW  
YORK, by LETITIA JAMES,  
Attorney General of the State of New York,

Plaintiffs,

v.

QUINCY BIOSCIENCE HOLDING  
COMPANY, INC., a corporation;

QUINCY BIOSCIENCE, LLC, a limited  
liability company;

PREVAGEN, INC., a corporation  
d/b/a SUGAR RIVER SUPPLEMENTS;

QUINCY BIOSCIENCE  
MANUFACTURING, LLC, a limited liability  
company;

MARK UNDERWOOD, individually and as  
an officer of QUINCY BIOSCIENCE  
HOLDING COMPANY, INC., QUINCY  
BIOSCIENCE, LLC, and PREVAGEN, INC.;  
and

MICHAEL BEAMAN, individually and as an  
officer of QUINCY BIOSCIENCE HOLDING  
COMPANY, INC., QUINCY BIOSCIENCE,  
LLC, and PREVAGEN, INC.,

Defendants.

Case No. 1:17-cv-00124-LLS

**DEFENDANTS QUINCY BIOSCIENCE HOLDING CO., INC., QUINCY BIOSCIENCE,  
LLC, PREVAGEN, INC., AND QUINCY BIOSCIENCE MANUFACTURING, LLC'S  
MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION TO STRIKE  
AFFIRMATIVE DEFENSES PURSUANT TO FED. R. CIV. P. 12(f)**

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Defendants Quincy Bioscience Holding Company, Inc., Quincy Bioscience, LLC, Prevagen, Inc. d/b/a Sugar River Supplements, and Quincy Bioscience Manufacturing, LLC (collectively “Quincy”), by their undersigned counsel, respectfully submit this memorandum of law in opposition to the Motion filed by the Federal Trade Commission (“FTC”) and the People of the State of New York, by Letitia James, Attorney General of New York (“NYAG”) (collectively, “Plaintiffs”) to Strike Affirmative Defenses Pursuant to Fed. R. Civ. P. 12(f) (the “Motion”). (Dkt. No. 86.)

### **PRELIMINARY STATEMENT**

Plaintiffs’ motion to strike certain of Quincy’s affirmative defenses attempts to create a new heightened pleading standard for affirmative defenses that has no basis in the Federal Rules of Civil Procedure or applicable case law. Motions to strike, such as the present motion, are strongly disfavored in the Second Circuit and should be denied unless it is clear that the allegations in question can have no possible bearing on the subject matter of the litigation. That is not the case here.

Quincy’s affirmative defenses should all be sustained at this early stage of the litigation. Plaintiffs do not argue that Quincy’s defenses are untimely, and therefore their challenge is limited to the factual and legal sufficiency of the defenses. There is no question that Plaintiffs are on notice of the factual basis for each of Quincy’s affirmative defenses. Plaintiffs do not argue otherwise. The facts supporting Quincy’s defenses are contained either in the affirmative defenses themselves or in Plaintiffs’ own allegations in the Complaint. Thus, each of Quincy’s defenses satisfies the relaxed plausibility standard adopted by the Second Circuit earlier this year in *GEOMC Co. v. Calmare Therapeutics Inc.*, and Quincy is entitled to further develop these defenses during discovery. Plaintiffs’ attempt to impose a heightened pleading standard is contrary to the Second Circuit’s decision and should be rejected.

Nor have Plaintiffs established the legal insufficiency of any of the challenged affirmative defenses. None of Quincy's affirmative defenses were adjudicated on the merits as a result of Quincy's motion to dismiss, which only considered the sufficiency of the allegations contained in Plaintiffs' Complaint. Plaintiffs' argument that other defenses are "not available as a matter of law" also lacks merit. The Motion is filled with misstatements or mischaracterizations of Quincy's defenses in an attempt to set up straw man arguments for dismissal. Quincy's defenses are all legally "available" and should be sustained.

Plaintiffs' conclusory assertions of prejudice should also be rejected. Plaintiffs do not argue that Quincy's defenses are untimely. Thus, as the Second Circuit recently reaffirmed in *GEOMC*, no amount of prejudice would warrant the drastic remedy of striking a defense, even if it would otherwise expand the scope of the litigation. To the extent prejudice is relevant at all, however, Plaintiffs' unsupported assertions of "relitigation" and "unnecessary and invasive discovery" are wholly conclusory and divorced from the actual facts of the case. Indeed, the discovery relating to Quincy's defenses is almost entirely duplicative of the discovery Plaintiffs will be required to collect to prove their affirmative claims. There is no prejudice to Plaintiffs at this early stage in the litigation.

Finally, in the event that the Court is inclined to grant any part of Plaintiffs' Motion, Quincy respectfully requests leave to file an amended answer pursuant to Rule 15(a)(2).

### **FACTUAL BACKGROUND AND PROCEDURAL HISTORY**

FTC filed its Complaint on January 9, 2017 alleging that Quincy's advertising and marketing statements regarding the dietary supplement PrevaGen® ("PrevaGen") are "false or misleading" or "not substantiated at the time . . . [they] were made," and that these representations violate Sections 5(a) and 12 of the Federal Trade Commission Act ("FTC Act"), Sections 349 and 350 of the New York General Business Law ("NY GBL"), and Section 63(12) of the New York

Executive law. (Complaint, ¶¶ 37, 38, 41, 43, 44 (Dkt. No. 1.)) After extensive briefing before this Court and the Second Circuit on Quincy’s motion to dismiss, Quincy filed its Answer to the Complaint on August 7, 2019 (the “Answer”). (Dkt. No. 73.) In its Answer, Quincy asserted seventeen affirmative defenses. (Answer at 8-10.) Plaintiffs’ Motion challenges eight of those defenses.

## **ARGUMENT**

### **I. LEGAL STANDARD**

Motions to strike affirmative defenses are generally disfavored in the Second Circuit and should be denied unless it is clear that the allegations in questions can have no possible bearing on the subject matter of the litigation. *See Colonial Funding Network, Inc. for TVT Capital, LLC v. Epazz, Inc.*, 252 F. Supp. 3d 274, 287 (S.D.N.Y. 2017) (Stanton, J.) (quoting *Lipsky v. Commonwealth United Corp.*, 551 F.2d 887, 893 (2d Cir. 1976) (“[C]ourts should not tamper with the pleadings unless there is a strong reason for doing so.”)). Indeed, under Rule 12(f) of the Federal Rules of Civil Procedure, matters can only be stricken from a pleading if they are “redundant, immaterial, impertinent, or scandalous.” Fed. R. Civ. P. 12(f); *see also Nat’l Union Fire Ins. Co. of Pittsburgh, PA. v. Cooper*, No. 85 CIV. 8750 LLS, 1990 WL 55690, at \*7 (S.D.N.Y. Apr. 26, 1990) (Stanton, J.). That is not the case here.

Historically, courts in the Second Circuit have required plaintiffs to satisfy a stringent three-pronged test to prevail on a motion to strike affirmative defenses: (1) there must be no question of fact that might allow the defense to succeed; (2) there must be no substantial question of law that might allow the defense to succeed; and (3) the plaintiff must be prejudiced by the inclusion of the defense. *See Colonial Funding Network*, 252 F. Supp. 3d at 288. This test was recently re-visited (and the first prong was slightly refined) by the Second Circuit in *GEOMC Co. v. Calmare Therapeutics Inc.*, 918 F. 3d 92 (2d Cir. 2019).



**A. Quincy’s Affirmative Defenses Are Subject to a Relaxed Plausibility Standard**

When the referenced three-prong test was first articulated, the relevant pleading standard was that of *Conley v. Gibson*, 355 U.S. 41 (1957). Under *Conley*, a complaint was not to be dismissed for failure to state a claim “unless it appear[ed] beyond doubt that the plaintiff [could] prove no set of facts in support of his claim which would entitled him to relief.” *Id.* at 45-46. Of course, this pleading standard has since changed to a “plausibility” standard under *Iqbal* and *Twombly*. See *GEOMC*, 918 F.3d at 98; *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007); *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009). In *GEOMC*, the Second Circuit took the logical and largely unremarkable step of extending the “plausibility” pleading standard to affirmative defenses. *GEOMC*, 918 F.3d at 98.

Plaintiffs’ Motion reads far too much into *GEOMC*, arguing that the Second Circuit created a new “heightened pleading standard” for affirmative defenses. (Motion at 2.) That is an overstatement. In fact, the word “heightened” is nowhere to be found in the decision and is expressly contrary to its holding. Plaintiffs created this new, “heightened” standard. Indeed, in *GEOMC*, the Second Circuit explained that application of the plausibility standard to any pleading is a context specific task. See *GEOMC*, 918 F.3d at 98. Moreover, in the context of an affirmative defense, one “aspect of the context [that] matters” is that the “pleader of a complaint has the entire time of the relevant statute of limitations to gather facts necessary to satisfy the plausibility standard.” *Id.* In contrast, the pleader of an affirmative defense has only the limited time to respond to the complaint in accordance with the Federal Rules of Civil Procedure. *Id.* The court also recognized that facts needed to plead certain affirmative defenses “may not be readily known to the defendant” without comprehensive discovery. *Id.* Such “circumstance[s] warrant[] a relaxed application of the plausibility standard” when pleading an affirmative defense. *Id.* In

sum, the Second Circuit seems to have settled somewhere in between the old *Conley* standard and the new *Twombly/Iqbal* standard, requiring defendants to plead affirmative defenses with more detail than they had in the past, but certainly not imposing on them the full burden of satisfying *Iqbal* and *Twombly*. Nothing in the decision suggests the “heightened” pleading standard requested in Plaintiffs’ Motion.

Following the *GEOMC* decision, courts in this District have held that “*GEOMC* does not stand for the proposition that an affirmative defense must be pleaded with the same degree of factual detail as a complaint.” *New London Assocs., LLC. v. Kinetic Social LLC*, No. 18cv7963 (DLC), 2019 WL 2918163, at \*1 (S.D.N.Y. July 8, 2019).

**B. Quincy’s Affirmative Defenses Should Be Sustained Unless Plaintiffs Can Establish That There Are No Questions of Law That Might Allow Them To Succeed**

*GEOMC* did not revise the second prong of the test. *See GEOMC*, 918 F.3d at 98. Thus, a motion to strike should be granted only in the rare circumstances where a plaintiff is able to establish that there are *no* substantial questions of law that might allow the defense to succeed. *See Colonial Funding Network*, 252 F. Supp. 3d at 288.

**C. Plaintiffs’ Conclusory Assertions of Prejudice Cannot Defeat Quincy’s Valid and Timely Affirmative Defense**

Finally, with respect to the third prong of the test – prejudice – *GEOMC* confirmed that “a factually sufficient and legally valid defense should *always* be allowed if timely filed even if it will prejudice the plaintiff by expanding the scope of the litigation.” *GEOMC*, 918 F.3d at 98. Since Plaintiffs are not arguing that any of Quincy’s defenses are untimely, their conclusory assertions of prejudice (including the relitigation of defenses and unnecessary and invasive discovery) should be disregarded because these defenses are all factually and legally sufficient. Plaintiffs’ claim of prejudice is speculative. But even if prejudice were properly considered,

Plaintiffs are unable to establish it with the requisite level of detail sufficient to warrant the striking of any of Quincy's defenses.

As will be discussed in more detail below, Quincy's affirmative defenses allege sufficient facts to plausibly suggest Quincy's ability to succeed, are appropriate as a matter of law, and are not defeated by Plaintiffs' conclusory assertions of prejudice.

## **II. PLAINTIFFS' MOTION TO STRIKE SHOULD BE DENIED IN ITS ENTIRETY**

### **A. None of Quincy's Defenses Have Been Adjudicated**

Plaintiffs assert that Quincy's First, Fifth, Sixth, and Fifteenth Affirmative Defenses should be stricken because they "have already been fully briefed, and were either rejected by this Court or the Second Circuit, or were withdrawn by Defendants after informal oral briefing before this Court." (Motion at 4.) Plaintiffs are wrong on all accounts.

As an initial matter, when deciding a motion to dismiss under Fed. R. Civ. P. 12(b)(6), a court is merely "assess[ing] the legal feasibility of the complaint." *Quinn v. Walgreen Co.*, 958 F. Supp. 2d 533, 540 (S.D.N.Y. 2013). As such, the court is not required to adjudicate any defense on the merits. *Id.* Quincy is therefore entitled to assert its affirmative defenses in its Answer and pursue the necessary discovery to enable it to prove these defenses at trial. *GEOMC*, 918 F.3d at 98. And even if the Court did resolve Quincy's defenses on the merits (which it did not), Quincy is entitled to preserve those defenses for the purpose of any future appeal.

#### **i. First Defense: Failure to State a Claim**

Plaintiffs' request to strike Quincy's First Affirmative Defense for failure to state a claim should be denied. (Motion at 4.) It is "well settled [] that a failure-to-state-a-claim defense can properly be asserted as an affirmative defense in an answer." *See Cnty. Vanlines Inc. v. Experian Info. Solutions, Inc.*, 205 F.R.D. 148, 153 (S.D.N.Y. 2002) (internal quotation marks omitted); *see also Coach, Inc. v. Kmart Corps.*, 756 F. Supp. 2d 421, 432 (S.D.N.Y. 2010); *Erickson Beamon*

*Ltd. v. CMG Worldwide, Inc.*, No. 12 CIV. 5105 NRB, 2014 WL 3950897, at \*4 (S.D.N.Y. Aug. 13, 2014). Courts in this District routinely recognize that a failure-to-state-a-claim defense is analogous to a general denial, results in “no prejudicial harm to plaintiff,” and therefore “the defense need not be stricken.” *Board of Managers of Trump Tower at City Center Condominium v. Palazzolo*, 346 F. Supp. 3d 432, 472 (S.D.N.Y. 2018); *see also Coach, Inc.*, 756 F. Supp. at 432 (“[A] failure to state a claim defense is not vulnerable to motions because the defense is analogous to a general denial and . . . does not prejudice plaintiffs.”). Quincy’s failure to state a claim defense should be sustained.

Moreover, contrary to Plaintiffs’ position, Quincy’s defense has not been fully and finally adjudicated. When resolving Quincy’s motion to dismiss, the Second Circuit found that “Plaintiffs had made *plausible allegations* that Quincy’s marketing campaign for Prevagen contained deceptive representations.” *FTC v. Quincy Bioscience Holding Co., Inc.*, 753 Fed App’x 87, 89 (2d Cir. 2019) (emphasis added). That determination was made at the pleading stage. Furthermore, the Court made all reasonable inferences in Plaintiffs’ favor on Quincy’s motion to dismiss. *See Rescuecom Corp. v. Google, Inc.*, 562 F.3d 123, 127 (2d Cir. 2009). This is not the same as an adjudication of the merits.

ii. Fifth Defense: Ultra Vires Act

Next, Plaintiffs argue that the Court has already adjudicated Quincy’s Fifth Affirmative Defense that FTC’s filing of the Complaint constitutes an *ultra vires* act. (Motion at 5.) When considering a motion to dismiss, courts analyze the legal sufficiency of the complaint, accept the plaintiff’s allegations as true, and resolve all reasonable inferences in the plaintiff’s favor. *See Rescuecom Corp. v. Google, Inc.*, 562 F.3d 123, 127 (2d Cir. 2009). They do not resolve factual issues on the merits. Accordingly, when the Court ruled on Quincy’s renewed motion to dismiss

following remand from the Second Circuit, it did not reject Quincy's defense that the filing of the Complaint was an *ultra vires* act. It simply held that Plaintiffs' allegations were sufficient to state a claim. *See FTC v. Quincy Bioscience Holding Co., Inc.*, 389 F. Supp. 3d 211, 215-16 (S.D.N.Y. 2019) ("consider[ing] the remaining issues on the motions to dismiss[,] including "the validity of the FTC quorum").

This defense goes to the heart of FTC's ability to pursue and maintain this action, and Quincy's Answer contains sufficient factual matter to put FTC on notice of its factual basis. Quincy specifically alleged that FTC's filing of the Complaint "constitutes an *ultra vires* act because it lacked a valid quorum of Commissioners to authorize its filing." (Answer at 8 (emphasis added).) This is plainly sufficient under the relaxed plausibility standard adopted in *GEOMC*, and Plaintiffs' claim that Quincy should have pled additional facts is without merit. This is especially apparent because the information relating to this defense is solely in FTC's possession and, contrary to Plaintiffs' argument, Quincy did not have "more than two years since the Complaint was filed to develop facts related to" its *ultra vires* defense. (Motion at 3.) No discovery had taken place as of the filing of Quincy's Answer, and Quincy had no other way to obtain additional factual information to support this defense other than the discovery process that the parties are now engaged in.

Given Quincy's lack of knowledge of (and access to) the relevant facts, Quincy's defense raises a plausible claim sufficient to warrant further discovery on the issue. Accordingly, the Court should deny Plaintiffs' Motion to strike Quincy's Fifth Affirmative Defense.

iii. Fifteenth Defense: The Geographical Scope of the New York GBL Claims

Quincy's Fifteenth Affirmative Defense states that "[t]he alleged conduct complained of in the Complaint involves transactions or acts that took place outside of New York. As a result, the claims under New York General Business Law §§ 349 and 350 fail." (Answer at 10.) Plaintiffs improperly conflate this defense with Defendant Underwood's personal jurisdiction defense and then argue that the Court "specifically rejected" this defense in its July 2019 opinion. (Motion at 5.)<sup>1</sup> Plaintiffs' argument is both disingenuous and incorrect, and should be rejected.

Quincy's Fifteenth Affirmative Defense has nothing to do with personal jurisdiction. Rather, it challenges the geographical scope of NYAG's GBL claims, which only apply to transactions that occur in New York and only authorize recovery on behalf of New York residents. *See, e.g.*, N.Y. G.B.L. § 349 ("Deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service *in this state* are hereby declared unlawful.") (emphasis added); N.Y. G.B.L. § 350 ("False advertising in the conduct of any business, trade or commerce or in the furnishing of any service *in this state* is hereby declared unlawful.") (emphasis added). Contrary to Plaintiffs' suggestion otherwise, Quincy did not raise this defense in its original motion to dismiss or its supplemental briefing, and the Court has not yet had the opportunity to consider it. (Motion at 5.)

Nor can Plaintiffs seriously question the factual basis for this defense, as it is contained in their own affirmative allegations, as well as in Quincy's Answer. Quincy is challenging NYAG's claims under GBL Section 349 and 350 to the extent Quincy's sales "took place outside of New York." (Answer at 10.) Plaintiffs allege that Quincy marketed and sold Prevagen throughout the United States and on that basis have therefore admitted that at least some transactions occurred

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<sup>1</sup> Lack of personal jurisdiction was raised as Defendant Underwood's Second Affirmative Defense, but was not raised in Quincy's Answer.

outside of New York State. (Complaint (Dkt. No. 1) ¶ 21.) Thus, Plaintiffs have sufficient notice of the factual basis for Quincy’s defense and no further factual matter is required to be pled.

Moreover, Plaintiffs have failed to even identify the relevant legal issue, much less establish that there is “no substantial question of law that could that might allow Quincy to prevail on this defense.” *Colonial Funding Network*, 252 F. Supp. 3d at 288.

Finally, Plaintiffs will not suffer any prejudice as a result of Quincy’s assertion of its fifteenth defense. NYAG has the burden to prove that alleged violations of the GBL occurred in New York State and, presumably, will seek discovery on that issue. Any discovery Quincy seeks with respect to this defense will likely be identical, eliminating any concern that the defense would increase the discovery burden on Plaintiffs. Plaintiffs’ Motion to strike Quincy’s Fifteenth Affirmative Defense should be denied.

iv. Sixth Defense: First Amendment

Plaintiffs next argue that “Defendants seek to revive a previously withdrawn First Amendment Defense.” (Motion at 5.) Again, this argument is disingenuous and expressly contradicted by the record. Quincy has not withdrawn its First Amendment defense and, in fact, expressly preserved it in its June 4, 2019 letter to the Court (Dkt. No. 61) and in its Answer. (Answer at 8.)

Quincy briefed this argument in its initial motion to dismiss (Dkt. No. 34 at 22-24), and Plaintiffs admit that “this Court never formally ruled on” it. (Dkt. No. 45 at 13; Motion at 6.) Quincy subsequently informed the Court prior to submitting its supplemental briefing that it would “withdraw [its] argument that this action constitutes an improper restraint on commercial speech from their motion to dismiss, *without prejudice and subject to being reasserted as an affirmative defense* and/or for other purposes throughout the litigation, if necessary.” (Dkt. No. 61 (emphasis

added).) Plaintiffs have failed to explain how this express reservation results in withdrawal of the defense.

Nor can Plaintiffs establish that there is “no substantial question of law that might allow the defense to succeed.” *See Colonial Funding Network*, 252 F. Supp. 3d at 288. Their position is premised on the legal principle that “deceptive commercial speech is not entitled to any protection under the First Amendment.” (Motion at 6.) Even assuming the validity of this legal principle, Plaintiffs’ argument puts the cart before the horse. There has been no finding that any of Quincy’s advertisements are deceptive, and therefore whether the advertisements are entitled to First Amendment protection remains to be seen. Indeed, whether or not the challenged advertisements are deceptive is the central question in this case, and will be the subject of extensive fact and expert discovery. Thus, it is not appropriately disposed of on a motion to strike. *See Estee Lauder, Inc. v. Fragrance Counter, Inc.*, 189 F.R.D. 269, 271-72 (S.D.N.Y. 1999) (“a motion to strike for insufficiency was never intended to furnish an opportunity for the determination of disputed and substantial questions of law[.] . . . particularly [when] there has been no significant discovery.”) (quoting *William Z. Salcer et al. v. Envicon Equities Corp.*, 744 F.2d 935, 939 (2d Cir. 1984)). Plaintiffs’ *allegations* of falsity and deception simply do not carry the day on a motion to strike, and courts have routinely denied FTC’s motions to strike First Amendment defenses in similar cases. *See Fed. Trade Comm’n v. Stratford Career Inst.*, No. 16-CV-371, 2016 WL 3769187, at \*3 (N.D. Ohio July 15, 2016) (denying motion to strike First Amendment defense because it involved a “dispositive issue” in the case and therefore “would not prejudice the [FTC] or burden discovery, given the similarities between the dispositive issue and defense”); *Fed. Trade Comm’n v. Nat’l Urological Grp., Inc.*, No. 1:04-CV-3294-CAP, 2005 WL 8155166, at \*8 (N.D.



Ga. June 24, 2005) (declining to strike First Amendment defense in false advertising case involving dietary supplements).

Plaintiffs' citation to *FTC v. Stefanchik*, No. C04-1852RSM, 2004 WL 5495267, at \*2 (W.D. Wash. Nov. 12, 2004) (Motion at 6), is misplaced at best, as the Western District of Washington applied a standard that is completely at odds with the standard that governs motions to strike filed in the Southern District of New York. As discussed above, to prevail on a motion to strike affirmative defenses in this District, a plaintiff must satisfy a stringent three-pronged test: (1) the defendant must allege facts that plausibly suggest the defendant's success on the defense; (2) there must be no substantial question of law that might allow the defense to succeed; and (3) the plaintiff must be prejudiced by the inclusion of the defense. *See GEOMC*, 918 F.3d at 98; *Colonial Funding Network*, 252 F. Supp. 3d at 288. This is a far cry from the *Stefanchik* court's assumption "that the facts alleged are true and can be proven by plaintiff." 2004 WL 5495267, at \*2. In fact, in this District, "courts generally apply the same test used to determine a Rule 12(b)(6) motion" as they do to motions to strike; in other words, courts will "draw all reasonable inferences in the" defendant's favor, and "resolve all doubts in favor of denying the motion to strike." *Diesel Props.v. Greystone Business Credit II LLC*, No. 07 CIV. 9580 (HB), 2008 WL 4833001, at \*4 (S.D.N.Y. Nov. 5, 2008). *See also Board of Managers*, 346 F. Supp. 3d at 471 ("[t]he standard that applies to a motion to strike is the 'mirror image' of the standard on a 12(b)(6) motion to dismiss for failure to state a claim"); *Estee Lauder, Inc.*, 189 F.R.D. at 269, 271 (S.D.N.Y. 1999) (on a motion to strike, it is "the *defendant's* pleadings [that] must be construed liberally," not the plaintiff's). *Stefanchik* is directly contrary to case law in this District and should be disregarded.

Moreover, it is undisputed that Quincy relied on extensive research—including a randomized, double-blinded, placebo-controlled human clinical trial—to support their claims

about the effects of Prevagen on memory and related cognitive functions. Nevertheless, Plaintiffs seek to restrict Quincy from speaking to the public about the results of these studies by imposing a heightened substantiation burden far beyond what the FTC Guidance and established case law require. Previous attempts by the FTC to impose such heightened restrictions have been struck down on First Amendment grounds based on the Supreme Court’s test for commercial speech as set forth in *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 47 U.S. 557 (1980). *See, e.g., POM Wonderful, LLC, v. FTC*, 777 F.3d 478, 499-505 (D.C. Cir. 2015) (finding FTC’s Order that categorically required two randomized controlled tests for substantiating disease claims to fail *Central Hudson*’s commercial speech scrutiny).

Finally, Plaintiffs have not – and cannot – identify any prejudice that would result from Quincy’s assertion of its First Amendment defense. As discussed above, the substantiation for Quincy’s advertisements, and whether or not those advertisements are deceptive, are the central issues in this case. Quincy’s First Amendment defense will not require any discovery on top of what Plaintiffs will seek to try to prove their affirmative claims and Plaintiffs cannot argue that they are subject to any prejudice as a result.

**B. Quincy’s Defenses Are Legally Proper**

Plaintiffs’ next overarching challenge to Quincy’s affirmative defenses is that the defenses are “not available . . . as a matter of law” or have “no legal relevance.” (Motion at 7, 9.) Quincy hereby respectfully withdraws its Second Affirmative Defense (laches and waiver), but maintains that its Tenth Affirmative Defense (good faith), Thirteenth Affirmative Defense (primary jurisdiction) and Seventeenth Affirmative Defense (reservation of rights) are proper under applicable law.

i. Tenth Defense: Good Faith

As with Quincy's GBL defense, Plaintiffs misconstrue Quincy's defense only to then seek to have it stricken on some irrelevant principal of law. This straw man approach should be rejected.

Quincy does not dispute that intent to defraud is irrelevant to whether an actual violation of Section 5 FTC Act or Sections 349 and 350 of the GBL have occurred, and did not assert good faith as a defense to liability. Rather, Quincy specifically alleged (and Plaintiffs ignored) that its good faith defense "prohibits Plaintiffs from obtaining any injunctive relief." (Answer at 9.) Courts across the country have routinely denied FTC's motions to strike good faith defenses where, as here, the defense is offered against the granting of a permanent injunction. *See, e.g., Fed. Trade Comm'n v. Stratford Career Inst.*, 2016 WL 3769187, at \*3 (denying motion to strike good faith defense because it was relevant to the court's determination of appropriate relief); *Fed. Trade Comm'n v. Debt Relief USA, Inc.*, No. 3:11-CV-2059-N, 2012 WL 13024099, at \*2 (N.D. Tex. Apr. 19, 2012) (denying motion to strike good faith defense because it "is neither insufficient nor irrelevant"); *Fed. Trade Comm'n v. Johnson*, No. 2:11-CV-02203-RLH, 2011 WL 2112258, at \*2 (D. Nev. May 26, 2011) (declining to strike good faith defense because "it is not immaterial or impertinent, as it may affect the relief granted if liability is established"); *Fed. Trade Comm'n v. Affiliate Strategies, Inc.*, No. 09-4104-JAR, 2010 WL 11470103, at \*10 (D. Kan. June 8, 2010); *Fed. Trade Comm'n v. USA Fin., LLC*, No. 8:08-CV-899-T-17MAP, 2009 WL 10671254, at \*2 (M.D. Fla. Feb. 18, 2009) (declining to strike good faith defense because a defendant's "intent may be relevant to the determination of appropriate relief"); *Fed. Trade Comm'n v. Nat'l Urological Grp., Inc.*, 2005 WL 8155166, at \*12 (declining to strike good faith defense to the extent it is offered against the granting of a permanent injunction).

The reasoning behind these cases is sound. Permanent injunctive relief is only proper where there exists some cognizable danger of recurring violation. *See Fed. Trade Commission v. Nat'l Urological Grp.*, 2005 WL 8155166, at \*12. “To determine whether a violation is likely to recur, the court may consider the deliberateness and seriousness of the violation, as well as the violator’s own history of unfair advertising practices.” *Id.* Thus, if Quincy had a good faith basis for its advertising, such good faith would weigh against the granting of injunctive relief.

Nor should Quincy be required to specifically plead the facts surrounding its good faith defense, because those facts are already clearly spelled out in Plaintiffs’ Complaint. Indeed, the Complaint does not allege that Quincy created its marketing claims from thin air. Quite the contrary, Plaintiffs *admit* that Quincy conducted a “double-blind, placebo-controlled human clinical study using objective outcome measure of cognitive function.” (Compl. ¶ 28.) And while Plaintiffs may disagree with the results of that study and/or Quincy’s analysis of those results, such disagreement does not prevent this Court from concluding, at the appropriate time and with the benefit of full discovery, that Quincy acted in good faith and that injunctive relief is not warranted.

Moreover, similar to other defenses, Quincy’s assertion of good faith will not increase the discovery burden on Plaintiffs and the relevant discovery will be similar, if not identical, to discovery on Plaintiffs’ affirmative claims.

ii. Thirteenth Defense: Primary Jurisdiction

Plaintiffs’ challenge to Quincy’s Thirteenth Affirmative Defense that Plaintiffs’ claims fall within the primary jurisdiction of the Federal Food and Drug Administration (“FDA”) is also without merit. Plaintiffs admit, because they must, that “[i]t is true that the FDA and FTC share overlapping authority over the regulation of foods, supplements, over-the counter drugs, and other health-related products.” (Motion at 9.) Plaintiffs further admit that, under a memorandum of

understanding between the FTC and FDA, “the FTC has generally taken the enforcement lead where the false or misleading claims for dietary supplements appear predominantly in advertising, and the FDA has generally taken the lead where such claims are limited to labeling.” (Motion at 10.) Plaintiffs’ Complaint clearly challenges the statements made on Prevagen’s labeling which, under Plaintiffs’ own agreement with FDA, falls within FDA’s province. Indeed, in the Joint Report Pursuant to Fed. R. Civ. P. 26(f), Plaintiffs set forth their position of “[t]he issues in this case” as including “whether the advertising, marketing, and *labeling* of Prevagen conveyed the challenged claims about memory and cognitive benefits.” (Dkt. No. 59 at 4 (emphasis added); *see also* Complaint, ¶ 1 (seeking relief for alleged violation “in connection with the labeling” of Prevagen); *id.* ¶ 27 (challenging statements on Prevagen’s labeling).) Accordingly, Plaintiffs admit that the claims they are challenging may fall within the FDA’s jurisdiction. Given these admissions, there is simply no basis to strike Quincy’s affirmative defense at this early stage of the litigation.

In fact, Plaintiffs’ own case cited for support of their position, *FTC v. Lunada Biomedical, Inc.*, No. CV-15-3380, 2015 WL 12911515 (C.D. Cal. Sept. 23, 2015), *confirms* that Quincy’s primary jurisdiction defense is proper. In *Lunada Biomedical*, the FTC challenged the defendants’ affirmative defense that the action was *ultra vires* because that “FTC action seeks to impose standards that diverge from clear FDA policies and, in doing so, oversteps the FTC’s authority to regulate advertising specifically . . . [in] an area to which the FDA generally exercises plenary authority” because the FTC sought to impose substantiation standards for a weight-loss supplement that exceeded the threshold that the FDA imposed for pharmaceuticals. *Id.* at \*4. While the court granted, with leave to amend, the FTC’s request to strike that defense, it specifically noted that “[a]t the hearing, counsel for Defendants argued for the first time that the

FTC's enforcement action also concerns [the supplement's] product packaging. According to the FTC, the FDA has primary jurisdiction to regulate labeling, and the standard that the FTC requires for [the supplement's] labeling could give rise to an agency conflict and, consequently, Defendants' *ultra vires* defense." *Id.* at \*5. Because those allegations with respect to the challenged products' labeling had not previously been raised by the defendants in that action, however, the court struck the defense with leave to amend. *Id.* Here, Plaintiffs clearly challenge the labeling of Prevagen, which, as Defendants set forth in the motion to dismiss, complied with both FDA labeling requirements and FTC's advertising guidance for dietary supplement manufacturers. Because Prevagen complies with FDA's labeling requirements, Quincy's primary jurisdiction defense is proper.

Moreover, none of Plaintiffs' other authority stands for the proposition that a primary jurisdiction affirmative defense should be stricken. *Thompson Med Co. v. FTC*, 791 F.2d 189, 193 (D.C. Cir. 1986), involved the review of an FTC order regarding the efficacy of claims of an over-the-counter-drug, not a dietary supplement like Prevagen. There, the court found that the FTC was not "indefinitely barred from all regulatory authority over drug advertising while the FDA conducts its comprehensive review of drug safety." *Id.* at 192. That decision is not applicable to the instant matter of whether or not Defendants may assert a primary jurisdiction defense. Similarly, *FTC v. Wellness Support Network, Inc.*, No. 10-cv-04879-JCS, 2013 WL 5513332, at \*1 (N.D. Cal. Oct. 4, 2013), does not support Plaintiffs' position. *Wellness Support Network* involved the FTC's motion to exclude expert testimony. *Id.* There, the court did not need to decide whether or not a challenged product was categorized as "medical food" or a "drug" under FDA regulations because it found the challenged expert's "reliance on the regulatory scheme under the FDA, as opposed to scientific principles, to support his analysis does not satisfy *Daubert's*

requirement that an expert must offer ‘scientific knowledge.’” *Id.* at \*10. Accordingly, Plaintiffs’ request to strike Quincy’s primary jurisdiction affirmative defense should be denied.

iii. Seventeenth Defense: Reservation of Rights to Add Affirmative Defenses

Plaintiffs also take issue with Quincy’s Seventeenth Affirmative Defense, which “reserves the right to raise additional affirmative and/or other defenses as may be established by discovery and other evidence developed during the pendency of this action. (Answer at 10.) Contrary to Plaintiffs’ assertion, this is not “a blanket reservation of future, unspecified defenses,” nor does it “violate[] the fair notice requirements of [Rule 8]” or “ignore[] the requirements of [Rule 15] for amended or supplemental pleadings.” (Motion at 11.) Rather, it is intended to put Plaintiffs on notice of the possibility that Quincy may, in the future, seek leave to amend its Answer consistent with the confines of Rule 15.

Where, as here, Quincy “recognize[s] the constraints imposed by Rule 15 and do[es] not purport to take upon [itself] any greater rights than those provided under the Federal Rules” a reservation of the right to raise additional affirmative defenses is proper. *In re Beacon Assocs. Litig.*, No. 09 CIV. 777 LBS AJP, 2011 WL 3586129, at \*6 (S.D.N.Y. Aug. 11, 2011). Moreover, Plaintiffs have not identified, nor could they identify, any prejudice from a defense that simply mirrors what Quincy is already entitled to do under the Rules, *i.e.* file a motion for leave to amend. *See id.* Indeed, Plaintiffs’ own cases recognize that Quincy is permitted to seek leave to amend under Rule 15 if and when new facts arise during discovery that support additional defenses. *See, e.g., County Van Lines, Inc. v. Experian Info. Solutions, Inc.*, 205 F.R.D. 148, 157-58 (S.D.N.Y. 2002) (Motion at 11). Plaintiffs’ motion to strike Quincy’s Seventeenth Affirmative Defense should be denied.

**III. QUINCY SHOULD BE GRANTED LEAVE TO AMEND ITS ANSWER IF NECESSARY**

To the extent the Court finds that any of Quincy's affirmative defenses are not sufficiently pled, Quincy respectfully requests leave to file an Amended Answer with additional factual allegations to support those defenses. *See U.S. v. Sikorsky Aircraft Corp.*, 382 F. Supp. 3d 860, 868 (E.D. Wis. 2019). Under Rule 15 of the Federal Rules of Civil Procedure, the court should freely give leave to amend a pleading when justice so required. Fed. R. Civ. P. 15(a)(2).

**CONCLUSION**

For the foregoing reasons, Plaintiffs' Motion to Strike Affirmative Defenses Pursuant to Fed. R. Civ. P. 12(f) should be denied or, in the alternative, Quincy should be granted leave to file an amended answer pursuant to Rule 15 of the Federal Rules of Civil Procedure.

Dated: September 30, 2019  
New York, New York

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**CERTIFICATE OF SERVICE**

I hereby certify that on this 30<sup>th</sup> day of September, 2019, a copy of the foregoing was file via Electronic Case Filing. Notice of this filing will be sent to all parties via the Court's Electronic Case Filing System.

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